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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,741	08/04/2000	Brent Belding	ACS-53498(21061)	2770

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,741

Applicant(s)

BELDING ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 6,10,12,27,29,39 and 45-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11,13-26,28,30-38 and 40-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-61, drawn to a catheter assembly, classified in class 604, subclass 103.05.
- II. Claims 62-64, drawn to a method of delivering an endoprosthesis, classified in class 604, subclass 28.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case product as claimed can be used in a materially different process of using that product. The catheter assembly of Group I does not require a balloon to inflate the stent after the sheath is inflated. The stent can be self-expanding.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) Expansion Mechanisms

- a. Figures 1-6
 - b. Figures 7A-7B
 - c. Figure 16
- 2) Catheter configuration
- d. Figure 8
 - e. Figure 9

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (ex. Group I, species 1c and 2d OR Group II, species 1a and 2e) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Thomas H. Majcher on 4/30/02 a provisional election was made without traverse to prosecute the invention of Group I, species 1a and 2d, claims 1-5, 7-9, 11, 13-26, 28, 30-38 and 40-44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6, 10, 12, 27, 29, 39 and 45-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sheath secured to the distal end of the *catheter tube*, as required by claim 35, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 33 is objected to because of the following informalities: on line 4, it appears that "polyurethane" is a repeat of "polyurethanes" on line 3, and should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 18-26, 28, 30-34 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 14, 31 and 41 contain the trademark/trade name "ESTANE". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph.

See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

A trademark or trade name is used to identify a source of goods, and not the goods themselves.

Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to

identify/describe a polyurethane and, accordingly, the identification/description is indefinite.

See MPEP 2173.05(u).

5. Claim 18 is indefinite because it is inaccurate, according to the specification and

drawings. In the embodiment shown in Figures 1-6, when inflation fluid is introduced into the means for expanding, the means for retaining is not configured to *detach* from the means for

delivering. It remains attached to the means for delivering. In the embodiment shown in Figures 7A-7B, the means for retaining is configured to detach from the means for delivering when

inflation fluid is introduced into the space between the means for retaining and means for delivering, not into the means for expanding. Applicant must clearly and accurately claim the invention of the elected embodiment.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-5, 7-9, 11, 13, 16-31, 33-41, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwab et al. (USPN 5,749,852) in view of Stone et al. (USPN 5,843,027).

Schwab et al. discloses a catheter assembly with all the elements of claims 1, 18 and 35, but is silent to the limitation of an endoprosthesis, specifically a stent (claims 9 and 26), being disposed on the expandable member. See Figure 12 and abstract for catheter (12) having an expandable member (10) on the distal end portion of the catheter and a sheath (18) disposed on the catheter. The inclusion of openings (32) configures the sheath such that it is capable of rupturing during expansion of the expandable member. Stone et al. teaches a catheter having an inflatable balloon with a stent mounted thereon in Figure 1 and column 4, lines 58-60. Examiner contends that it is old and well known in the art to have a stent mounted onto a balloon portion of a catheter in order to for the stent to expand and hold open a vessel in an area suffering from stenosis upon inflation of the balloon. It would have been obvious to one of ordinary skill in the

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art at the time of applicant's invention to modify the catheter assembly of Schwab et al. to include a stent on the balloon in order to for the assembly to be able to hold and maintain open a vessel suffering from stenosis in addition to providing perfusion. Schwab et al. is also silent to the additional limitation of the catheter including an over-the-wire intravascular catheter, as required by claims 11, 28, 37 and 38. Applicant admits that an over-the-wire catheter is old and well known in the art on pages 20-21, lines 26-2 and Figure 8 of the specification and taught by Stone et al. in column 3, lines 21-29 and shown in Figure 1. Because this type of catheter is standard in the art, it would have been obvious for the catheter assembly of Schwab et al. to include an over-the-wire catheter.

Claims 2, 3, 19, 20 and 36, see Figure 12, element 32 for circumferential perforations. Inclusion of the openings configures the sheath to be capable of rupturing during expansion of the expandable member.

Claims 4, 5, 7 and 21-24, see column 2, lines 20-26, column 4, lines 46-52 and column 5, lines 16-18 for sheath being stretched prior to be secured to the balloon/distal end of catheter.

Claims 8 and 25, see Figure 12, element 10 for expandable member being balloon.

Claims 13, 16, 17, 30, 31, 33, 34, 40, 41, 43 and 44, see column 4, lines 53-58 for sheath being formed from the elastomeric material, polyurethane. ESTANE is simply a trademark name of polyurethane.

8. Claims 14, 15, 32 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwab et al. in view of Makower et al. (USPN 6,302,875 B1).

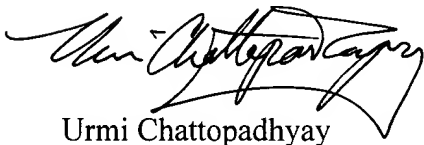
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Schwab et al. discloses a catheter assembly with all the elements of claims 1, 18 and 35, but is silent to the additional limitation of the sheath being formed from a polyurethane, ESTANE, with a shore hardness of 45D or lower or a biodegradable material, as required by claims 14 and 15, 32, 42, respectively. Makower et al. teaches a catheter with a sheath formed from a polyurethane having a shore hardness of less than 45D or a biodegradable material, elastin, in order to impart a less rigid and less hard region in the sheath. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Makower et al. to make the sheath of Schwab et al. of a polyurethane having a shore hardness of less than 45D or a biodegradable material in order to impart less rigid and hard characteristics to the sheath so that it will expand with less pressure. See column 7, lines 9-28.

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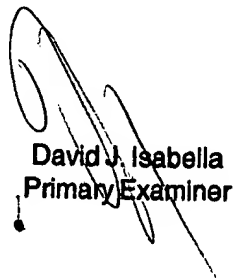
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner

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May 3, 2002